DETAILED ACTION

Status of the claims

1. Claims 1-21 are pending. Claims 1-3, 7-9 and 13 are under examination.

Election/Restrictions

2. Applicant's election without traverse of Group I in the reply filed on 8/2/11 is acknowledged.

3. Claims 4-6, 10-12 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/2/11.

Specification

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim I recite the limitation "an altered tomato gene sequence". An altered gene sequence reads on fragments of the sequence, including a single dinucleotide. Thus it fails to set forth the metes and bounds of the claimed invention. Amending the claims to read - - the altered tomato gene sequence - - or somehow indicating that the full length sequence is required, would overcome this rejection.

5. The term "altered" in claim 1 is a relative term which renders the claim indefinite. The term "altered" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. The term "at nucleotide 931" in claim 1 is a relative term which renders the claim indefinite. The term "at nucleotide 931" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

4. Claim 13 provides for the use of the method of claim 7, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

5. Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the flowing paragraph, a claim in dependent form shall contain a reference to the claim previously set forth and specify a further limitation of the subject matter claimed. A claim

> in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

7. Claim 13 is rejected under 35 U.S.C. 112, fourth paragraph, as failing to specify a further limitation. Claim 13, which depends from claim 7, recites "a means of post control-limitation in seed production". Claim 7 is a method for detecting the presence of hp-1 mutation in a plant, thus claim 13 fails to further limit claim 7.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a nucleotide sequence for an altered tomato DDB1 gene sequence or fragments. The altered sequence or fragments comprises an A-to-T transversion at nucleotide 931 of the altered tomato DDB1 sequence. The claims comprise a genus of nucleic acid sequence variants that are large and variable. The genus could encompass any number of nucleic acid sequences so long as the altered gene sequence or fragment comprises at least the A-to-T transversion at relative nucleotide 931 of SEQ ID NO 1. An altered gene sequence reads on fragments of the

sequence, including a single dinucleotide. Applicants have not provided any guidance on any common features that would reasonably convey to one of skill in the relevant art that they had possession of the claimed invention. Applicants have provided one sequence falling within the claimed genus but they have not described any variant species where the nucleic acids were different in any way from the disclosed SEQ ID NO: 1.

Description of SEQ ID NO: 1 for a nucleotide sequence for an altered tomato DDB1 gene sequence or fragment, is insufficient to describe the large and variant genus of genes (and ultimately proteins) so that the skilled artisan could envision and conclude that applicants are in possession of at least a substantial number of members of the claimed genus of nucleic acid variants.

10. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 does not reasonably provide enablement for fragments of an altered DDB1 sequence, i.e. the specification does not provide enablement for fragments of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a nucleotide sequence for an altered tomato DDB1 gene sequence or fragments. The altered sequence or fragments comprises an A-to-T transversion at nucleotide 931 of the altered tomato DDB1 sequence.

Applicants have not provided any guidance as to the size for the fragment SEQ

ID NO: 1 which would still provide for the tomato high pigment 1 (hp-1) phenotype. Applicants have not provided any distinguishing characteristics such as a correlation between a common structure and the effect on phenotype. Applicants have not taught the minimal fragment size which would provide for the hp-1 phenotype in tomatoes. The specification does not teach how to screen out the fragments that are not responsible for the hp-1 phenotype. Applicants have not taught how to make and use the claimed invention without undue trial and error experimentation to practice the invention within the scope of the claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-3, 7-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowler et al. US Patent No. 6,429,299, issued August 6, 2002 in view of Yen et al. 1997, Theor. Appl. Genet. 95: 1069-1079.

The claims are broadly drawn to a nucleotide sequence for an altered tomato DDB1 gene sequence or fragments. The altered sequence or fragments comprises an A-to-T transversion at nucleotide 931 of the altered tomato DDB1 sequence. The claims are also broadly drawn to a method of detecting the presence of hp-1.

Bowler et al. teach the isolation, sequencing and identification of hp-2 phenotype's underling genetic mutation relative to wild type. See Fig. 5; column 4 lines 41-67; column 7 lines 31-67. Bowler et al. teach isolation of genomic DNA, amplification of the gene fragment by PCR and determining the presence of the hp-2 mutation in Lycopersicon esculetnum. See column 7 lines 31-67; column 8 lines 1-40; column 9 lines 42-67; column 10, lines 1-22. Bowler et al. teach detecting hp-2 in tomato seeds. See column 6, lines 50-67. Bowler et al teach that the hp-1 and hp-1^{w} phenotypes are well known in the art having first been identified in 1917. See column 2 lines 20-31.

Bowler et al. do not teach hp-1 is an altered tomato DDB1 gene. Bowler et al. does not teach SEQ ID NO: 1 with an A-to-T transversion at nucleotide 931. Bowler et al. does not teach pyrosequencing technique nor does Bowler et al. teach comparison of SEQ ID NO: 1 sequence the newly obtained sequence data.

Yen et al. teach mapping the hp-1 gene locust to the tomato chromosome 2 as a first step towards isolation of the hp-1 gene. See page 1069, abstract, page 1070, second column second full paragraph. Yen et al. suggest the isolation and characterization of normal and mutant alleles of the hp gene as a part of the complete characterization of the hp phenotype. See page 1070, second column second full paragraph.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Bowler et al. with the teachings of Yen et al. to obtain the instant invention. Based on the abundant prior art of methodologies there is nothing in the specification to suggest that a slightly different technique, e.g. RACE sequencing verses pyrosequencing or comparing wt nucleic acid sequence vs mutant sequence, disclosed in the prior art would not yield the same polynucleotide of the instant invention. One of ordinary skill in the art would have been motivated to try to isolate and sequence the hp-1 gene based on the teachings Yen et al. that the hp-1 locus is on chromosome 2 and the predictability of success of Bowler et al. in isolating, sequencing and identifying the mutation of hp-2, with a reasonable expectation of success. The prior art teaches that the phenotype was well known and its physical location was mapped to chromosome 2. Having mapped the hp-1 gene to within 1 cM, it would have been a routine matter to

walk down the chromosome to sequence the hp gene. The prior art provides a motivation to isolate the gene so as to sequence it and identify the mutation. The prior art teaches well known and reliable methods for isolation of genomic DNA, sequencing, and further identifying the presence of the hp-1 mutation, that is the transversion at nucleotide 931 of A-to-T. Therefore, the instant invention is a product not of innovation but of ordinary skill and common sense. See IN RE Kubin 561 F.3d 1351 (Fed. Cir. 2009)

Claim Objections

Claim 13 is objected to as it depends from both claim 7 and to claim 10. Claim 10 is a non-elected invention thus the claim depends from a non-elected invention.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL ROATH whose telephone number is (571)270-1008. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne-Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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